EMA EudraVigilance and Signal Management Information Day

21 November 2023 | 09:30 – 17:00 CET | #23525

European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, NL

| PROGRAMME COMMITTEE

Paolo Alcini
Head of Healthcare Data
European Medicines Agency (EMA), EU

Georgy Genov
Head of the Pharmacovigilance Office
European Medicines Agency (EMA), EU

Rodrigo Postigo
Pharmacovigilance Office,
European Medicines Agency (EMA), EU

Gilles Touraille
Pharmacovigilance Office,
European Medicines Agency (EMA), EU

Anja van Haren
EudraVigilance Coordinator
Medicines Evaluation Board (MEB), NL

| SPEAKERS & PANELISTS

Sabine Brosch
Data Protection Officer,
European Medicines Agency (EMA), EU

Marcos Fernandez Gomez
Scientific Administrator,
European Medicines Agency (EMA), EU

Michelle Grimes
ICH E2D Expert Working Group member
Head, International Pharmacovigilance
MSD, UK

Veronica Lipucci Di Paola
Scientific Administrator,
European Medicines Agency (EMA), EU

Tom Paternoster-Howe
Scientific Administrator,
European Medicines Agency (EMA), EU

Loris Piccolo
Scientific Administrator,
European Medicines Agency (EMA), EU

Luis Pinheiro
Scientific Administrator,
European Medicines Agency (EMA), EU

Eugène Paul van Puijenbroek
EMA signal management review team (SMART)
Head of Scientific Department
Pharmacovigilance Centre Lareb, NL

Katharina Weber
PV Inspector and Assessor
Austrian Federal Office for Safety in Health Care/AGES, AT

Magnus Ysander
EU & UK QPPV & Head Pharmacovigilance Excellence,
AstraZeneca, SE

| OVERVIEW

One of the milestones during 2022 in the EudraVigilance database was the mandatory use of the ISO Individual Case Safety Report (ICSR) standard (ISO 27953-2:2011) based on the ICH E2B(R3) modalities and the ISO terminology on pharmaceutical dose forms and routes of administration, (ISO 11239:2012).

Following this important milestone, this information day will describe and highlight other aspects for further development in the database and initiatives driven by international activities, together with the management and maintenance of EudraVigilance for the good functioning of the EU pharmacovigilance network.

Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) applies since 25 May 2018. MAHs are controllers for the personal data processing activities carried out pursuant to the pharmacovigilance legislation including the access and further processing of ICSR data originating from EudraVigilance. The data protection activities, measures and responsibilities will be described and developed during this information day.

The European Medicines Agency (EMA) is implementing the ISO IDMP standards for the identification of medicinal products in a phased programme, based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (SPOR) data. An update of the SPOR activities will be highlighted.

According to Article 24 (3) of Regulation 726/2004, the Agency shall, in collaboration either with the MAHs or with the Member State that submitted an individual suspected adverse reaction report to the EudraVigilance database, be responsible for operating procedures that ensure the quality and integrity of the information collected. Moreover, specific quality system procedures and processes shall be in place to ensure submission of accurate and verifiable data on serious and non-serious suspected adverse reactions to the EudraVigilance database within the 15 or 90-day time frame [IR- Art 11 (1) (c)]. To support these legislative requirements, the Agency is working on the process to implement compliance reports for electronic submission of ICSRs. These reports and their implementation will be fully described during this information day.

The ICH E2D guideline was agreed at Step 4 in May 2003; In the meantime, new sources of post-approval safety information (e.g., social media, digital platforms, market research programs, patient support and assistance programs) have emerged or are more frequently utilised by marketing authorisation holders. The definitions and standards for the management of post-approval safety information are no longer sufficient to provide guidance on the current practices and needs; The E2D(R1) Expert Working Group is currently working on the revision and updates will be presented.

Other aspects such as the role of the EU QPPVs, quality control of ICSRs, pharmacovigilance inspections findings and examples of the use of artificial intelligence will be described.

| KEY TOPICS

- EudraVigilance data protection activities
- SPOR related activities with regard to product and substance data
- Revision of ICH- E2D
- ICSRs quality control
- Pharmacovigilance Inspections
- EudraVigilance Operational activities

| TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs) and their deputies
- Professionals involved in Pharmacovigilance, Safety Surveillance Scientists
- Sponsors of Clinical Trials
- Individuals involved in clinical development, information management, safety databases and safety assessment.

Pharmacovigilance Information Technology Professionals

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA | 21 NOVEMBER 2023 | 09:30 – 17:00 CET

09:30 **REGISTRATION**

09:50 **WELCOME NOTE BY SESSION CHAIRS**
Georgy Genov & Paolo Alcini, EMA

10:00 (25+10) **DATA PROTECTION WITH REGARD TO EUDRAVIGILANCE**
Sabine Brosch, EMA, EU

QUALITY ASPECTS RELATED TO EUDRAVIGILANCE

10:35 (20) **EU QPPV ROLE IN RELATION TO EUDRAVIGILANCE & SIGNAL MANAGEMENT**
Magnus Ysander, AstraZeneca, SE

10:55 (20) **PHARMACOVIGILANCE INSPECTIONS -KEY ASPECTS AND FINDINGS**
Katharina Weber, AGES, AT

Q&A with speakers and panellists

11:30 COFFEE BREAK

12:00 (20) **ICSR DATA QUALITY (FINDINGS) – DOS AND DON'TS**
Tom Paternoster-Howe, EMA, EU

12:20 (20) **GO-LIVE OF NEW EUDRAVIGILANCE REPORTING COMPLIANCE REPORTS**
Gilles Touraille, EMA, EU

12:40 (20) **UPDATE ON THE REVISION OF ICH E2D(R1) GUIDELINE**
Michelle Grimes, MSD, UK – ICH E2D Expert Working Group member

Q&A with speakers and panellists

13:00 LUNCH BREAK

14:00 (20) **MEDICAL LITERATURE MONITORING SERVICE – SIGNIFICANT UPDATES FOR MAHS**
Tom Paternoster-Howe, EMA, EU

14:20 (40) **SPOR ACTIVITIES WITH FOCUS ON PRODUCT AND SIGNAL DETECTION**
Marcos Fernandez Gomez & Veronica Lipucci Di Paola, EMA SPOR team, EU

Q&A with speakers and panellists

15:20 COFFEE BREAK

FUTURE TRENDS AT EMA

15:50 (20) **THE NEW EMA SIGNAL AND SAFETY ANALYTICS PROJECT - WHAT DOES IT MEAN FOR MAHS AND NCAS?**
Rodrigo Postigo & Loris Piccolo, EMA, EU

16:10 (20) **INSIGHTS FROM THE SMART METHODS TEAM ON NEW METHODOLOGIES USED IN EV**
Eugène Paul van Puijenbroek, Pharmacovigilance Centre Lareb, NL, EMA signal management review team (SMART)

16:30 (20) **OPPORTUNITIES TO USE ARTIFICIAL INTELLIGENCE IN SIGNAL DETECTION**
Luis Pinheiro, EMA, EU

Q&A with speakers and panellists

17:00 **CLOSING OF THIS INFORMATION DAY**

| Disclosure Policy
Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA.
Speakers and agenda are subject to change without notice.

REGISTRATION FORM | ID# 23525

EMA EudraVigilance and Signal Management Information Day
21 November 2023, 09:30-17:30 CET, EMA, Amsterdam, NL

You can register online at www.diaglobal.org/EMA/conference-listing

CATEGORY

Industry (or Representative)*	€ 500.00 ❑
Government/Patients/Academia/Non-Profit (Full-Time)	€ 250.00 ❑

A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA in Basel for more information.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Attendee email required to access presentations

Please provide your European VAT number

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID#23525 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA in Basel.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **http://www.diaglobal.org/EUTerms**.

Date	Signature

TERMS AND CONDITIONS

Cancellations

All cancellations must be made in writing and be received at the DIA office in Basel four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office in Basel of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, please click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CE(S)T.

Email Basel@DIAglobal.org
Tel. +41 61 225 51 51
Web www.DIAglobal.org
Mail DIA, Kuechengasse 16, 4051 Basel, Switzerland